Health Information Technology Advisory Committee

The Office of the National Coordinator for Health Information Technology

U.S. Core Data for Interoperability Task Force 2021
Report to the Health Information Technology Advisory Committee

PHASE 1 - RECOMMENDATIONS ON DRAFT USCDI VERSION 2 CONTENT

APRIL 15, 2021

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Background

Leveraging significant input from the Health IT Advisory Committee and its United States Core Data for Interoperability (USCDI) Task Force, in March, 2020, ONC published USCDI version 1, a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. The USCDI Task Force further provided recommendations on the expansion process ONC established to develop newer versions of USCDI that could be adopted by health IT developers and provided to their customers to improve interoperable health information exchange and patient access to their data. These recommendations included how to implement the ONC New Data Element and Class (ONDEC) submission system which received over 600 recommendations for new data elements for USCDI Version 2 (v2) in 2020.

On January 12, 2021, ONC published its Draft USCDI version 2 and sought public feedback on data elements included in this version, as well as on data elements that ONC did not include in it. As part of this public feedback process, ONC charged the HITAC to establish a new USCDI Task Force for 2021 to make specific recommendations on the content in the Draft USCDI v2, and to provide feedback on the entire process of expanding the USCDI in future versions.

ONC CHARGES TO THE USCDI TASK FORCE

Overarching Charge

The USCDI Task Force 2021 was charged with reviewing and providing feedback on the Draft USCDI Version 2 content and process.

Detailed Charge

The Task Force's specific charges were to provide recommendations on the following:

1. **(Due April 15, 2021)** Evaluate Draft USCDI v2 and provide HITAC with recommendations for:
   1a - Data classes and elements from USCDI v1 including applicable standards version updates
   1b - New data classes and elements from Draft USCDI v2 including applicable standards
   1c - Level 2 data classes and elements not included in Draft USCDI v2
2. **(Due September 9, 2021)** Evaluate the USCDI expansion process and provide HITAC with recommendations for:
   2a - ONDEC submission system improvements
   2b - Evaluation criteria and process used to assign levels to submitted data classes and elements
   2c - Prioritization process used by ONC to select new data classes and elements for Draft USCDI v2
3. **(Due September 9, 2021)** Recommend ONC priorities for USCDI version 3 submission cycle

ADDITIONAL BACKGROUND INFORMATION

The Task Force (TF) first assembled a robust group of subject matter experts across various stakeholder groups, including direct patient care, patient advocacy, health IT development, standards development organizations, and others. Over the course of its work, the TF made several changes to the membership, including changing representation from the DoD/VA, having two HITAC members resign due to conflicts, and adding representation from patient advocacy groups. The roster included in the Appendix to this document reflects the TF membership at the time these recommendations were finalized.

The TF applauds the work of the ONC in creating the USCDI Draft v2. We support the majority of the recommendations included in the draft, and appreciate the consideration given to the TF recommendations herein. The Task Force has expanded on the themes represented USCDI Draft v2 with diligence and thoughtfulness.

The Task Force established a method of recording individual member's recommendations related to specific data elements and data classes in the Draft USCDI v2 as well as data elements that were not included in Draft v2. Members were able to directly enter their recommendations so they could be discussed during Task Force meetings.

As the task force deliberated, we gave strong consideration to the review of standards applicable to each of the data elements being considered. Where USCDI, C-CDA and FHIR US Core standards intersected there was a bias to recommend these data elements for advancement in USCDI. The Task Force also considered the value of simultaneously including multiple related mature data elements within a data class in USCDI to align or reconcile with other efforts. Such alignment may mitigate confusion in the marketplace and make development efforts by vendors and adoption by users more efficient. The current TF recommendations reflect these biases, and this perspective will continue to inform our future efforts.

There are data elements in USCDI v1 as well as in Draft v2 that do not include specified terminology standards or supporting implementation guides. The task force was not tasked with reconciling this and understands that data put forward without associated standards may have compelling use cases and national importance to warrant inclusion. For some data elements the TF concluded that finalized implementation guides should be required prior to advancement to USCDI. In situations where such implementation guides do not yet exist the TF is suggesting that the HITAC formally request that HL-7 prioritize the necessary work to finalize such IGs so that these data classes/elements can be included in v2 or a subsequent version of USCDI. This perspective informs the TF's recommendations regarding additional data elements for inclusion in v2.

Tension exists where there are differing opinions on urgency of inclusion. For example, CMS submitted a number of recommendations that, although not considered urgent to support quality measures, have urgency in supporting clinical care. The task force has reviewed these elements and made specific recommendations.

Additionally, each stakeholder group may offer differing priorities. These stakeholders include: the data underserved (patients, families, public health, social services, tribal), providers, payers, regulators, researchers as well as those involved in quality management. The TF seeks guidance from HITAC regarding whether and how to prioritize USCDI advancement by stakeholder as we initiate the next phase of work.

Recommendations

INTRODUCTION

The focus of the 2021 USCDI TF in Phase 1 was to address charges 1a, 1b and 1c, to make specific recommendations based on ONC's Draft v2 to include, omit, revise or add specific data classes and elements in USCDI v2.

Unless otherwise indicated, all of the recommendations apply to USCDI v2.

High level recommendations include:

1. Add selected data classes and elements to v2 to support CMS's quality improvement and management efforts.
2. Add the Social Determinants of Health data elements which were determined by ONC to be Level 2, but which were not included in Draft v2.
3. Where standards exist, but final implementation guides are not in place, ONC should work explicitly with HL7 to prioritize completion of implementation guides to accommodate HITAC data element and data class recommendations.
4. Where congruence of standards exists between C-CDA and FHIR US Core, accelerate alignment and adoption through all regulatory efforts including USCDI.

LIST OF SPECIFIC RECOMMENDATIONS

Charge 1a - Data classes and elements from USCDI v1 including applicable standards version updates

- **USCDI-TF-2021-Phase 1_Recommendation 01 - Data Class: Assessment and Plan of Treatment; Data Element: Assessment and Plan of Treatment**
    - The TF recommends that ONC clarify, in v2, that the data element includes *both* assessment *and* plan of treatment detail for exchange - leveraging and building upon the overlap/intersection of FHIR US Core and C-CDA.

- **USCDI-TF-2021-Phase 1_Recommendation 02 - Data Class: Diagnostic Imaging**
    - The TF recommends that ONC clarify whether Diagnostic Imaging extends beyond Radiographic images to include visible light photographic or video images, e.g., from endoscopic studies. Recommend including specific examples as a part of the definition.

- **USCDI-TF-2021-Phase 1_Recommendation 03 - Data Class: Laboratory; Data Element: Tests**
  - The TF recommends that ONC provide clarification in v2 regarding the scope of the Laboratory Tests data element to clearly differentiate its contents from the Diagnostic Studies/Exams data class which the TF is recommending for inclusion in v2..

- **USCDI-TF-2021-Phase 1_Recommendation 04 - Data Class: Laboratory; Data Element: Values/Results**
  - The TF recommends that when values/results include a Unit of Measure, the Unified Code for Units of Measure (UCUM) should be used where available across standards. UCUM was developed by Regenstrief Institute and the UCUM Organization as an unambiguous system of units and their combinations. From the UCUM website:

  - Justification: The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans. A typical application of The Unified Code for Units of Measure are electronic data interchange (EDI) protocols, but there is nothing that prevents it from being used in other types of machine communication.
    UCUM has been adopted internationally by many organizations such as IEEE, DICOM, LOINC, and HL7, and is also in the ISO 11240:2012 standard.

- **USCDI-TF-2021-Phase 1_Recommendation 05 - Data Class: Problems; Data Element: Problems, defined by ICD-10-CM terminology standards**
  - The TF recommends that ICD10 be added as an allowable standard for coding of problem list diagnoses.

- **USCDI-TF-2021-Phase 1_Recommendation 06 - Data Class: Procedures**
  - The TF recommends that USCDI V2 include clarification of the definition and scope of the Procedures data class in light of the recommended addition of the Diagnostic studies and exams with results data class. Stakeholders desire a clear understanding of the differentiation between diagnostic studies and procedures, which are typically considered to be therapeutic in their purpose. Such clarification will support consistent industry adoption of these two related and complementary data classes.

Charge 1b - New data classes and elements from Draft USCDI v2 including applicable standards

- **USCDI-TF-2021-Phase 1_Recommendation 07 - Data Class: Care Team Members; Data Elements: Provider Identifier**
  - The TF recommends that the Provider Identifier data element be specified to include specification of the coding system and version that is utilized when populating the field.

- **USCDI-TF-2021-Phase 1_Recommendation 08 - Data Class: Care Team Members; Data Elements: Provider Identifier, Provider Name**
  - The TF recommends that the title of the Provider Name and Provider Identifier data elements be changed to Care Team Member Name and Identifier

  - Justification: Care teams contain members who are not licensed providers, including family members and other caregivers. It should be possible to capture the identity of these individuals as members of the care team and to access, exchange and use this data to support care coordination.

- **USCDI-TF-2021-Phase 1_Recommendation 09 - Data Class: Diagnostic Imaging; Data Element: Diagnostic Imaging Narrative**
  - The TF recommends removing the “Diagnostic Imaging Narrative” data element from the “Diagnostic Imaging” data class, and recommend that the definition of the Diagnostic Imaging Report data element be updated to clarify that a well structured document should include, where present, narrative notes to summarize findings, impressions, and conclusions, as well as information that may be encoded, whether qualitative or quantitative in nature.
  - This would result in the following data elements within the Diagnostic Imaging data class:
    - Diagnostic Imaging Order
    - Diagnostic Imaging Report (updated)

  - Justification: The USCDI v2 Draft proposal to create a new Diagnostic Imaging data class and move the Diagnostic Imaging Narrative to the new class was intended to emphasize that the structured and narrative portions of imaging reports should be included together just as they would exist in the original, source documents. This proposal is not intended to imply that the reports should contain narrative content only. For downstream standards development consideration beyond the USCDI, there should be no need for a separate LOINC code to represent a narrative-only report as it is not relevant whether the reports consists of narrative only, coded only, or a structured report with narrative, encoded, and quantitative data.

- **USCDI-TF-2021-Phase 1_Recommendation 10 - Data Class: Encounter Information; Data Element: Encounter Diagnosis**
  - The TF recommends that this data element specifically reference coded billing diagnoses for encounters.

- **USCDI-TF-2021-Phase 1_Recommendation 11 - Data Class: Encounter Information; Data Element: Encounter Time**
  - The TF recommends that ONC include greater clarification with examples. Include start/stop date and time (to the minute) for acute care encounters (ED, short stay, hospital). Would need to specify precisely what times constitute start and stop times.

  - Justification: The duration of encounters is utilized in CMS electronic clinical quality measures (eCQMs) and is beneficial for workflow management.

- **USCDI-TF-2021-Phase 1_Recommendation 12 - Data Class: Laboratory; Data Elements: Laboratory Report Narrative, Pathology Report Narrative**
  - The TF recommends removing the Laboratory Report Narrative and Pathology Report Narrative data elements from the Laboratory data class.

  - Justification: The USCDI v2 Draft proposal to move the Laboratory Report Narrative and Pathology Report Narrative data elements to the Laboratory data class was intended to emphasize that the structured and narrative portions of these reports should be included together just as they would exist in the original, source documents. However, it created a duplication of function between these narrative data elements and the existing Value/Result data element. Value/Result data already contains both structured, coded content as well as unstructured, narrative content. For downstream standards development consideration beyond the USCDI, there should be no need for a separate LOINC code to represent a narrative-only result as it is not relevant whether the result reports consist of narrative only, coded only, or a structured report with narrative, encoded, and quantitative data.

- **USCDI-TF-2021-Phase 1_Recommendation 13 - Data Class: Laboratory; Data Element: Value/Result**
  - The TF recommends that the definition of the Value/Result data element be updated to clarify that it should include, where present, narrative notes to summarize findings, impressions, and conclusions, as well as information that may be encoded, whether qualitative or quantitative in nature.
  - In combination, recommendations 12 and 13 would result in the following data elements within the Laboratory data class:
    - Tests

- Values/Results (updated)

- Justification: While the intent of ONC reclassifying Laboratory and Pathology Report Narrative elements into Laboratory data class was understandable, it created a duplication of function between these narrative data elements and the existing Value/Result data element. Value/Result data already contains both structured, coded content as well as unstructured, narrative content. Rather than duplicating the function of carrying narrative content, the recommendation is made to clarify that Value/Result must contain both structured and unstructured content, as available.This recommendation is not intended to imply that the results should contain narrative content only. For downstream standards development consideration beyond the USCDI, there should be no need for a separate LOINC code to represent a narrative-only result as it is not relevant whether the result reports consist of narrative only, coded only, or a structured report with narrative, encoded, and quantitative data.

Charge 1c - Level 2 data classes and elements not included in Draft USCDI v2

- **USCDI-TF-2021-Phase 1_Recommendation 14 - Data Class: Care Team Members; Data Elements: Provider Role, Provider Location, Provider Telcom Information, Provider NPI, Provider DEA Number.**
    - The TF recommends including in USCDI v2 data class Care Team Members all of the constituent data elements from Level 2. When added, each of the new data elements should have its title adjusted to utilize the term "Care Team" as opposed to "Provider". Collection of these data elements should be optional, but data should be available for access, exchange and use if available.

    - Justification: Care team members data are essential to transitions of care. Level 2 elements are well understood and documented. Supports communication and coordination between care team members and automation of information routing. Care Team Members data should include care members outside of the clinical setting, (e.g., social service and home care providers, as well as care partners).

- **USCDI-TF-2021-Phase 1_Recommendation 15 - Data Class: Diagnostic Studies and Exams with Results *(NEW Data Class)***
    - The TF recommends including the Diagnostic Studies and Exams data class in v2 with specification of the following studies to be included as part of testing/certification:
        - Colonoscopies - Including captured discrete data and textual interpretation but not requiring video, static, or derived images
        - Echocardiograms - Including discrete data, specifically the left ventricular ejection fraction, and textual interpretation but not requiring echocardiographic or derived images
        - Electrocardiograms - Including discrete data and textual interpretation but not requiring an image of the waveform
        - Pulmonary function tests - Including discrete data and textual interpretation but not requiring an image of the flow-volume loops
    - The TF recommends that v2 clarifies the definition of diagnostic studies and that this definition be as encompassing as possible.

    - Justification: Specific diagnostic studies are referenced by and used frequently to support CMS eCQMs. While some of these studies are required as part of the Diagnostic Imaging data class, including other data elements that meet Level 2 criteria will support patient management, including appropriate follow-up, outcomes measurement, and risk adjustment

- **USCDI-TF-2021-Phase 1_Recommendation 16 - Data Class: Encounter Information; Data Element: Encounter Disposition**
  - The TF recommends including in v 2 a requirement for Encounter Disposition for Hospital and ED encounters, including short stay.
  - The TF recommends that the HL7 code system be specified as the applicable standard for Discharge Disposition for testing.
  - Specification should cover discharges to home, to PAC, and hospice.

  - Justification: This data element is used for CMS eCQMs, for billing; collected by CEHRT; supports categorization of encounters, attribution, and accountability. Provides context for recent encounters/transfers that impact patient care and care decisions.

- **USCDI-TF-2021-Phase 1_Recommendation 17 - Data Class: Encounter Information; Data Element: Encounter Location**
  - The TF recommends including in v 2 the ability to specify the facility / organization ID for the organization as well as the physical location of an encounter utilizing Taxpayer Identification Number (TIN) and/or (CMS Certification Number) CCN at the Encounter level. These data would be optional and included when available.

  - Justification: Provider ID was added to USCDI draft v 2. We recommend adding this complementary requirement to support discrete identification of the organization and location where an encounter occurred.

  - Comment: ONC could determine that the collection and specification of this data would be more appropriate under the Facility Level Data class using the Facility Identifier and Facility Managing Organization Identifier data elements specified as Level 2.

- **USCDI-TF-2021-Phase 1_Recommendation 18 - Data Class: Medications; Data Element: Discharge Medications**
  - The TF recommends including this Data Element in v 2, contingent upon HL7 completing/providing implementation guides (IGs) for C-CDA and FHIR US Core.
  - The TF recommends that HITAC formally write to HL7 requesting their focus on this and other data elements that require additional IGs for inclusion in USCDI, including items that HITAC wants HL7 to focus on for Versions 3 and 4, etc.

  - Justification: Management of medications is critical to patient care and coordination between providers, as well as related patient safety and quality management efforts. Distinction of medications that are recommended and should be given to or taken by the patient after discharge is key to assuring safe transitions of care as well as coordination of care and patient / caregiver engagement.

- **USCDI-TF-2021-Phase 1_Recommendation 19 - Data Class: Orders; Data Element: Types of orders for medical care/services *(NEW Data Class)***
    - The TF recommends including this data class and element in v2.
    - The TF recommends that orders for end of life care be included in certification testing including orders for palliative care, hospice, comfort care.

    - Justification: Requiring standards-based interoperability of orders would bring needed flexibility to patients and providers, allowing orders to move more easily between organizations, facilitating patient choice and greater value. Requiring interoperability of end of life orders, in particular, can increase the likelihood that patients' wishes are respected as they transition between care settings and support patient autonomy and care coordination.

- **USCDI-TF-2021-Phase 1_Recommendation 20 - Data Class: Patient Demographics; Data Elements: Gender Identity, Sexual Orientation**
    - The TF recommends the inclusion of the Gender Identity and Sexual Orientation and data elements in USCDI v2.
    - Include in HITAC/ONC letter to HL7 a specific request to prioritize the relevant IGs for finalization as a prerequisite to adding these data elements to USCDI.

    - Justification: Gender identity was included in the 2015 Edition Demographics certification criterion and the 2015 Edition Base EHR definition, but was not included in the Common Clinical Data Set nor USCDI v1. The Level 2 write up explains the significant breadth of use, availability of standards, and lack of barriers.

- **USCDI-TF-2021-Phase 1_Recommendation 21 - Data Class: Patient Demographics; Data Element: Medicare Patient Identifier**
    - The TF recommends the inclusion of this data element, AKA the Medicare Beneficiary ID (MBI), contingent on HL7's completion of US core IG for coverages. If this can be done in time for inclusion in v 2 include it, if not hold for Version 3.

    - Justification: Data element is readily available, required for billing, and advances the linkage between billing and clinical EHRs, supports data aggregation across data sources and reduces burden, as well as attribution.

- **USCDI-TF-2021-Phase 1_Recommendation 22 - Data Class: Social Determinants of Health; Data Elements: Assessment, Goals, Interventions, Outcomes, Problems/Health Concerns *(NEW Data Class)***
    - The TF recommends the inclusion of this data class and all component Level 2 data elements contingent on HL7's completion of the relevant IGs.
    - Justification: Collection and use of SDOH data elements provide support for the social and behavioral factors which impact individuals disease state, treatment and care. These factors have been found to have particular importance in the context of the COVID-19 pandemic and the lack of access to this data has impaired optimal public health and clinical responses. These data elements reflect emerging industry standards and implementation guides.

Future Considerations

The TF seeks guidance from HITAC on guiding principles for USCDI expansion and decision making. These principles should inform our deliberation and would include stakeholder considerations, approaches to aligning policy levers for data element work in C-CDA and FHIR US Coreefforts, as well as aspirational goals for USCDI. The TF will present questions and considerations for these guiding principles in future HITAC meetings.

Task Force suggestion for consideration for USCDI Version 3:

- Encounter Information: The TF recommends that ONC signal that Encounter Disposition should be documented and exchanged for long term care facilities when possible.

- Encounter Information: The TF encourages further development work to mature data elements Reason for Encounter/Visit (currently Comment Level) data element and that would support free text entry of a patient's chief complaint in their own words.

- Orders: The TF encourages further development work to mature data elements for orders relevant to end of life care when ready, including DNR/DNI (Data element: Requested data element Obligation or Prohibition Instruction for Life Sustaining Treatment), POLST/MOLST (Data element: Portable Medical Orders for Life-Sustaining Treatments).

- Advance Directives: Orders: The TF encourages future inclusion of this data class and the six component data elements currently specified as Level 1.

- The TF encourages ONC to promote entire data classes, with all available data elements, in future versions of USCDI, where those data classes are mature, in general use, and congruent with standards already promoted in other regulations. Examples include: Facility Level Data, Patient Demographics. The TF also encourages ONC to consider expansions of USCDI that bring utility to new stakeholders.

Appendix A

Task Force Roster

Name	Organization
Steven Lane (Co-Chair)	Sutter Health
Leslie Kelly Hall (Co-Chair)	Engaging Patient Strategy
Ricky Bloomfield	Apple
Hans Buitendijk	Cerner
Grace Cordovano	Enlightening Results
Jim Jirjis	HCA Healthcare
Ken Kawamoto	University of Utah Health
John Kilbourne	VA
Leslie Lenert	Medical University of South Carolina
Clement McDonald	National Library of Medicine
Aaron Miri	The University of Texas at Austin, Dell Medical School and UT Health Austin
Brett Oliver	Baptist Health
Mark Savage	University of California, San Francisco's Center for Digital Health Innovation
Michelle Schreiber	CMS
Sasha TerMaat	Epic
Andrew Truscott	Accenture
Sheryl Turney	Anthem, Inc.
Daniel Vreeman	RTI International
Denise Webb	Indiana Hemophilia and Thrombosis Center